Attachment - Business Requirements

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I. GENERAL INFORMATION

A. Background:

This CR will be implemented over multiple releases

Medicare recognizes that a clinical diagnostic laboratory may refer a specimen to another clinical diagnostic laboratory for testing. Generally, Medicare requires that the entity that furnishes the service, in this case the clinical diagnostic laboratory that performs the test, bill for the service. However, § 1833(h)(5)(A)(ii) of the Social Security Act permits, under certain conditions, a clinical diagnostic laboratory to bill for a clinical diagnostic laboratory fee schedule service that was performed by another clinical diagnostic laboratory. This Transmittal updates the claims processing rules for processing claims submitted by independent clinical diagnostic laboratories when the claim is for a service referred by one laboratory to another.

Medicare uses certain terms of art in the context of laboratory-to-laboratory referrals. Medicare defines a referred clinical diagnostic laboratory service/test as a service performed by one laboratory at the request of another laboratory. "Referring laboratory" is defined as the laboratory that refers a specimen to another laboratory for testing. "Reference laboratory" is defined as the laboratory that receives a specimen from another laboratory and that performs one or more tests on such specimen.

Medicare's payment policy for laboratory services is, generally, based on fee schedules and each carrier jurisdiction has its own fee schedule. Many carriers have been unable to process a claim for a referred clinical diagnostic laboratory test when the test was performed in another jurisdiction because they did not possess the fee schedule of that other jurisdiction. Moreover, carriers have not been required to adjudicate a claim for a referred service furnished in another jurisdiction unless it happened to have available the clinical laboratory fee schedule for such jurisdiction. Thus, some carriers pay for referred services performed outside of their jurisdiction and some do not.

Some referring laboratories electing to bill for a referred service performed in another jurisdiction have been unable to have the claim processed by the carrier in which they are enrolled. These laboratories have attempted to overcome the difficulty by enrolling as a reference laboratory with the carrier having jurisdiction where the test was performed. Some carriers have permitted such enrollments and issued a Provider Identification Number (PIN) for the reference laboratory as a "reference-use-only" PIN. However, not every carrier has been willing to issue "reference-use-only" PINs.

These instructions resolve these issues by requiring that: 1) an independent clinical laboratory may bill only the carrier in which it is enrolled by reason of having a physical presence; 2) an independent clinical laboratory may not enroll with a carrier as a "reference-use-only" laboratory; 3) every carrier must adjudicate a claim for a referred service, regardless of where the service was performed, if the claim is submitted by a laboratory located in its jurisdiction; 4)

every carrier must pay for a referred service on the basis of the fee schedule in effect in the jurisdiction where the test was performed; 5) every carrier must cancel all existing "reference-use-only" enrollments and "reference-use-only" PINs and refrain from making any further "reference-use-only" enrollments; 6) the referring laboratory must identify a referred service as such on the claim and identify reference laboratory performing such test; and 7) both the referring laboratory and the reference laboratory must be enrolled in Medicare.

B. Policy:

Although Medicare payment may generally be made to an independent clinical laboratory only for those tests that it performs, payment may also be made to a laboratory for a test that are on the clinical laboratory fee schedule that it has referred to another laboratory, provided the referring laboratory meets one of the following three conditions:

- It is located in, or is part of, a rural hospital;
- It is wholly-owned by the reference laboratory; or both it and the reference laboratory are wholly-owned subsidiaries of the same entity; or
- It refers no more than thirty (30) percent of the clinical laboratory tests annually to other laboratories, (not including referrals made under the wholly-owned proviso, above).

The Medicare allowed amount for a referred test is based on the fee schedule in effect where the test was performed. For services that are carrier priced, the reimbursement amount will be based upon the price developed by the carrier processing the claim.

The billing laboratory, whether it is the referring laboratory or the reference laboratory, must submit its claim to the carrier in which it is enrolled by reason of having a physical presence.

When the billing laboratory is the referring laboratory it must:
- Identify the referred service as such by use of modifier 90, and
- Identify the reference laboratory by specifying its CLIA number and address (i.e., the address where the test was actually performed).

<u>General Requirements</u>

- Disenroll out-of-jurisdiction laboratories that were previously enrolled for the purpose of billing referred services and cancel all "reference-use-only" PINs;
- Reject claims submitted by out-of-jurisdiction laboratories;
- Process claims submitted for referred services from an independent clinical laboratory enrolled in its jurisdiction by reason of having a physical presence within its jurisdiction;
- Reject as unprocessable a claim for a referred test (identified by the modifier 90) if the claim does not specify (for each item so identified) the address and CLIA number of the reference laboratory;
- Maintain the laboratory fee schedules for all carrier jurisdictions; and
- Base the payment amount of a referred service on the fee schedule of the jurisdiction in which the test was performed (Use the numerical locality code to identify the appropriate fee schedule; this data is available on the clinical diagnostic lab fee schedule) or, if such fee schedule does not have

a price for the referred service, the carrier must base the payment amount on its own fee schedule amount or, if none, on a price it develops.

Paper Claim Submission

Provider Information

Suppliers that submit claims in the paper format (CMS 1500 claim form) may not combine services that they performed themselves and any that they referred to another laboratory on the same CMS 1500 claim form. If a billing laboratory performs some testing and refers the remaining tests to another (referral) laboratory to perform, the laboratory must split the claim and submit two separate claims. If services are referred to more than one laboratory, a separate claim must be submitted for each laboratory that services were referred to. Referral laboratory claims submitted to carriers are permitted only for independent clinical laboratories, specialty code 69. The performing laboratory's name and address must be reported in item 32 on the CMS-1500 form to show where the service (test) was actually performed.

CLIA Number

A paper claim for laboratory testing requires the presence of the CLIA number performing the testing in item 23 on the CMS-1500 billing form. A claim for laboratory testing must be submitted as follows:

- Paper Claim: the billing laboratory performs all laboratory testing.

The facility submits a single claim for CLIA-covered laboratory tests and reports the CLIA number of the billing laboratory that is performing the testing in item 23 on the CMS-1500 form.

- Paper Claim: Billing laboratory performs some laboratory testing; some testing is referred to another laboratory.

If a billing laboratory performs some testing and refers the remaining tests to another (referral) laboratory to perform, the facility must split the claim and submit two separate claims. Paper claims will be returned as unprocessable if billing providers combine clinical lab services performed themselves and any referred to another lab on the same CMS 1500 form. On each claim, the CLIA number of the laboratory that is actually performing the testing must be reported in item 23 on the CMS-1500 form. Referral laboratory claims are permitted only for independently billing clinical laboratories, specialty code 69.

Example: a physician has ordered the ABC Laboratory to perform carcinoembryonic antigen (CEA) and hemoglobin testing for a patient. Since the ABC Laboratory is approved to perform tests only within the hematology LC level (which includes the hemoglobin test), it refers the CEA testing (which is a routine chemistry LC) to the XYZ laboratory.

The ABC laboratory submits a claim for the hemoglobin test and reports its CLIA number in item 23 on the CMS-1500 form. Since the ABC laboratory referred the CEA test to the XYZ laboratory to perform, the ABC laboratory (billing laboratory) submits a second claim for the CEA testing, reporting XYZ's CLIA number in item 23 on the CMS-1500 form. The XYZ laboratory's name, and address is also reported in item 32 on Form CMS-1500 to show where the service (test) was actually rendered.

Electronic Claim Submission

American National Standards Institute (ANSI) X12N 837 (HIPAA version) format electronic claims:

CLIA number:

An ANSI claim for laboratory testing will require the presence of the performing (and billing) laboratory's CLIA number; if tests are referred to another laboratory, the CLIA number of the laboratory where the testing is rendered must also be on the claim. An ANSI electronic claim for laboratory testing must be submitted using the following format:

- ANSI Electronic claim: the billing laboratory performs all laboratory testing.

  The independent laboratory submits a single claim for CLIA-covered laboratory tests and reports the billing laboratory's number in:
  X12N 837 (HIPAA version) loop 2300, REF02. REF01 = X4

- ANSI Electronic claim: billing laboratory performs some laboratory testing; some testing is referred to another laboratory.

  The ANSI electronic claim will not be split; CLIA numbers from both the billing and reference laboratories must be submitted on the same claim. The presence of the '90' modifier at the line item service identifies the referral tests. Referral laboratory claims are only permitted for independently billing clinical laboratories, specialty code 69.

The billing laboratory submits, on the same claim, tests referred to another (referral/rendered) laboratory, with modifier 90 reported on the line item and reports the referral laboratory's CLIA number in:
X12N 837 (HIPAA version) loop 2400, REF02. REF01 = F4

Example: A physician has ordered the DEF independent laboratory to perform glucose testing and tissue typing for a patient. Since the DEF Laboratory is approved to perform only at the routine chemistry LC level (which includes glucose testing), it refers the tissue-typing test to the GHI laboratory.

The DEF laboratory submits a single claim for the glucose and tissue typing tests; the line item service for the glucose test is submitted without a '90' modifier since the DEF laboratory performed this test. The CLIA number for the DEF laboratory is entered in the electronic claim in:
X12N 837 (HIPAA version) loop 2300, REF02. REF01 = X4

On the same claim, the line item service for the tissue typing test is submitted with a '90' modifier and the referral/rendering GHI laboratory's CLIA number is entered on the electronic claim in:
X12N 837 (HIPAA version) loop 2400, REF02. REF01 = F4

Reference Laboratory's Address

An electronic claim for laboratory testing requires the presence of the performing and billing laboratory's, name and address. The performing laboratory for a service with a line item CPT 90 modifier requires provider information for the X12N 837 in Loop 2420C.

National Standard Format (NSF) Electronic Claims:

CLIA number:

An NSF claim for laboratory testing will require the presence of the performing (and billing) laboratory's CLIA number: if tests are referred to another laboratory, the CLIA number of the laboratory where the testing is rendered must be on the claim. An NSF electronic claim for laboratory testing must be submitted using the following format:

The electronic claim will not be split; CLIA numbers from both the billing and reference laboratories must be submitted on one claim. The presence of the '90' modifier at the line item identifies the referral tests The CLIA number reported on line items with modifier 90 will be the CLIA number of the performing clinical diagnostic laboratory. Referral laboratory claims are only permitted for independently billing clinical laboratories, specialty code 69. The CLIA number shall be reported in:

FA0 – 34.0

Reference Laboratory's Address

An NSF electronic claim for laboratory testing requires the presence of the performing and billing laboratory's, name and address. The performing laboratory for a service with a line item CPT '90' modifier requires provider information to be submitted in the following NSF record and fields:

FB0 – 27.0 Name
FB0 – 28.0 Address 1
FB0 – 29.0 Address 2
FB0 – 30.0 City
FB0 – 12.0 State
FB0 – 31 Zip

C. Provider Education:

Carriers shall inform affected providers by posting either a summary or relevant portions of this document on their Web site within two weeks. Also, carriers shall publish this same information in their next regularly scheduled bulletin. If they have a listserv that targets affected providers, they shall use it to notify subscribers that information about Processing of Claims for Referred Services for an Independent Clinical Diagnostic Laboratory is available on their Web site.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
1	**All carrier standard systems shall make all of the clinical laboratory fee schedules for the entire United States available to all of their carriers for the processing of diagnostic laboratory claims.**	**Standard Systems**

2	**All carrier standard systems shall process claims for clinical laboratory services based upon where the service is performed when the line item contains a modifier 90.**	**Standard Systems**
3	**All carriers shall provide payment for referred services diagnostic laboratory claims based upon the fee schedule amount for where the service is performed.**	**Standard Systems**
4	**All carrier standard systems shall make the determination of the appropriate fee schedule amount for paper claims on all of the line items based upon the zip code in Item 32 on the Paper HCFA-1500 and for electronic claims for referral services (modifier 90), based upon the zip code reported in X12N 837 Loop 2420C. The zip code is in the N4 segment, element N403 Postal Code.**	**Standard Systems**
5	**All carriers shall identify all independent clinical laboratories enrolled that do not have a physical presence in their jurisdiction and cancel the PIN. Notify the supplier of the action taken.**	**Carriers**
6	**Carrier Standard Systems shall assign a distinct locality code for specialty 69 claims only based upon the clinical laboratory fee schedule. This code can be found on the clinical laboratory fee schedule.**	**Standard Systems**
7	**CWF shall bypass the locality code edit (74x1) for specialty type 69.**	**CWF**

II. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
N/A	

B. Design Considerations:

X-Ref Requirement #	Recommendation for Medicare System Requirements
N/A	

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: April 1, 2004 **Implementation Dates: April 5, 2004** **Pre-Implementation Contact(s):** **Joan Proctor-Young (410) 786-0949** **Tracey Hemphill (410) 786-7169** **Post-Implementation Contact(s): Regional Office**	**These instructions should be implemented within your current operating budget**